K130361

APR 2 2013

5. 510(k) Summary

A. Submission date: 01/21/2013

B. Applicant:
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B. Contact Person
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C. Proprietary and Established Names
- Common Name: Non-Contact Infrared Thermometer
- Classification Name: Clinical Electronic Thermometer
- Trade Names: 1. Thermofinder
  2. Thermocare
- Establishment Registration Number: 3008729744
- Product Code and Classification Panel: FLL, 21 CFR 880.2910
- Regulatory Classification: Class II

D. Predicate device: The Infrared Forehead Thermometer, FS-300&301 (K101912)

E. Intended use
The Non-Contact Infrared Thermometer is intended for measurement and monitoring of human body temperature.

F. Device Description
The Non-Contact Infrared Thermometer is an electronic thermometer using an infrared sensor (thermopile) to measure forehead temperature. Its operation is based on measuring the natural thermal radiation emanating from the forehead and the adjacent surfaces. Its software performs a calculation that factors in room temperature, and then a calculated temperature is displayed on the LCD.

G. Technological Characteristics:

The Non-Contact Thermometer has the exact same technological characteristics as the predicate device. In fact, the predicate device is the same device with the same intended use, specifications, materials, etc.. The only difference between the current device and its predicate is the 'Indication for Use', which will change from Rx to OTC. The specifications of the device are summarized below:

Measurement method	Infrared measurement, Contactless measurement
Measurement range	Object : 15.0°C ~ 60.0°C Body : 34.0°C ~ 42.5°C

	Only FS-301 Specifications Humidity :20 ~ 90% RH
Accuracy	Object : 15.0°C ~ 60.0°C : ±2.0°C Body : 34.0°C ~ 35.9°C : ±0.3°C 36.0°C ~ 39.0°C : ±0.2°C 39.1°C ~ 42.5°C : ±0.3°C Only FS-301 Specifications Humidity : 20% ~ 90% : ±10%
Display format	LCD display
Display unit	0.1°C
Power idle mode	After 60 seconds
Measurement time	Less than 2 second
Battery	LR03(AAA) (2EA) at least 5,000 measurements
Weight	120g (without holder and batteries)

H. Performance (Safety and Effectiveness Information)
The Non-Contact Infrared Thermometer has been manufactured and tested to meet the following safety and effectiveness requirements:

- IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.
- IEC 60601-1-2: Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004); Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004).
- IEC 60601-1-4: Medical Electrical Equipment - Part 1-4: General Requirements for Safety -- Collateral Standard: Programmable Electrical Medical Systems, Edition 1.1.
- ISO 14971: Medical Devices - Application of Risk Management to Medical Devices.

I. Conclusion:

Technically the device is exactly same as its predicate device (K101912). The 510(k) changes its indication from Prescription (Rx) use to Over-The-Counter (OTC) use.

The performance tests demonstrate that the Non-Contact Infrared Thermometer is as safe, as effective and performs in a substantially equivalent manner to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Hubdic Company, Limited
C/O Mr. David Yungvirt
Responsible Third Party Official
Pharmalink Technical Group, LLC
20 F Street, NW
Washington, District of Columbia 20001

April 2, 2013

Re: K130361
Trade/Device Name: Infrared Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: March 16, 2013
Received: March 19, 2013

Dear Mr. Yungvirt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 130361

Device Name:
Non-Contact Infrared Thermometer

Indications:
The Non-Contact Infrared Thermometer is intended for measurement and monitoring of human body temperature.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use __X__
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH. Office of Device Evaluation (ODE)

FDA
Richard C. Chapman
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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